

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

YK0030

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2005/001902

International filing date (day/month/year)

09.02.2005

Priority date (day/month/year)

13.02.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant

KABUSHIKI KAISHA YAKULT HONSHA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/001902

Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

This opinion has been established on the basis of a translation from the original language into the following language

_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☐

in written format

☐

in computer readable form

c. time of filing/furnishing

☐

contained in the international application as filed.

☐

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/001902

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3	YES
	Claims	1, 2, 4, 5	NO
Inventive step (IS)	Claims	3	YES
	Claims	1, 2, 4, 5	NO
Industrial applicability (IA)	Claims	1-5	YES
	Claims		NO

2. Citations and explanations:

Documents Cited in the ISR

Document 1: US 6653319 B1

Document 2: JP 03-004077 B

Document 3: JP 2004-277374 A

Claims 1, 2, 4, and 5

Claims 1, 2, 4, and 5 do not appear to possess novelty or involve an inventive step.

Document 1 cited in the ISR describes the use of cyclodextrin and acetic acid buffer solution in obtaining preparation of poorly water-soluble camptothecins (see example 9 in particular).

Claim 3

Claim 3 appears to possess novelty and involve an inventive step.

None of the documents 1-3 cited in the ISR describe or suggest the advantages of solubility over other acids when combining 7-ethyl-10-piperidinopiperidinocarbonyloxy camptothecin with acetic acid and sodium acetate.

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Applicant

KABUSHIKI KAISHA YAKULT HONSHA

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- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
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Name and mailing address of the ISA/JP

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/001902

Box No. I

Basis of this opinion

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☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
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 - a. type of material
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
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	Claims	<u>1, 2, 4, 5</u>	NO
Inventive step (IS)	Claims	<u>3</u>	YES
	Claims	<u>1, 2, 4, 5</u>	NO
Industrial applicability (IA)	Claims	<u>1-5</u>	YES
	Claims	<u></u>	NO
2. Citations and explanations:			
<u>Documents Cited in the ISR</u>			
Document 1: US 6653319 B1			
Document 2: JP 03-004077 B			
Document 3: JP 2004-277374 A			
<u>Claims 1, 2, 4, and 5</u>			
Claims 1, 2, 4, and 5 do not appear to possess novelty or involve an inventive step.			
Document 1 cited in the ISR describes the use of cyclodextrin and acetic acid buffer solution in obtaining preparation of poorly water-soluble camptothecins (see example 9 in particular).			
<u>Claim 3</u>			
Claim 3 appears to possess novelty and involve an inventive step.			
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